UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

MITCHELL LUDY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 1:19-cv-04606-JMS-DLP
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

ORDER

Pro se Plaintiff Mitchell Ludy filed this lawsuit against Defendant Eli Lilly and Company ("Lilly"), alleging that he suffered withdrawal side effects after attempting to discontinue use of the drug Cymbalta, and that Lilly failed to warn of the possibility of those side effects. Lilly has filed a Motion to Dismiss, [Filing No. 14], which is now ripe for the Court's decision.

I.
STANDARD OF REVIEW

Under Rule 12(b)(6), a party may move to dismiss a claim that does not state a right to relief. The Federal Rules of Civil Procedure require that a complaint provide the defendant with "fair notice of what the . . . claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007)). In reviewing the sufficiency of a complaint, the Court must accept all well-pled facts as true and draw all permissible inferences in favor of the plaintiff. *See Active Disposal Inc. v. City of Darien*, 635 F.3d 883, 886 (7th Cir. 2011). A Rule 12(b)(6) motion to dismiss asks whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). But the complaint "need not identify legal theories, and specifying an incorrect legal theory is not a

fatal error." *Rabe v. United Air Lines, Inc.*, 636 F.3d 866, 872 (7th Cir. 2011). The Court will not accept legal conclusions or conclusory allegations as sufficient to state a claim for relief. *See McCauley v. City of Chi.*, 671 F.3d 611, 617 (7th Cir. 2011). Factual allegations must plausibly state an entitlement to relief "to a degree that rises above the speculative level." *Munson v. Gaetz*, 673 F.3d 630, 633 (7th Cir. 2012). This plausibility determination is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.*

II.
BACKGROUND

The following are the factual allegations set forth in the Complaint, which the Court must accept as true.

Lilly is a large drug manufacturing company headquartered in Indianapolis, Indiana. One of the drugs Lilly manufactures is Cymbalta, which can be used to treat pain, among other things. [Filing No. 14-1 at 2.] The prescribing information for Cymbalta[1] provides, in part:

[1] In ruling on a motion to dismiss, the Court may consider "documents that are attached to the complaint, documents that are central to the complaint and are referred to in it, and information that is properly subject to judicial notice." *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013). Courts may take judicial notice of an "adjudicative fact" if the fact "is not subject to reasonable dispute because it (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The prescribing information available from the Food and Drug Administration ("FDA") website meets these criteria, and therefore the Court will consider the Cymbalta prescribing information as it existed in 2017, the year Mr. Ludy was prescribed Cymbalta. *See Ossim v. Anulex Techs., Inc*, 2014 WL 4908574, at *2 (S.D. Ind. Sept. 30, 2014) (taking "judicial notice of FDA 510(k) letters exhibits because the information is publicly and readily available from the FDA"); *Boston v. Boehringer Ingelheim Pharm., Inc.*, 2012 WL 3021413, at *2 (S.D. Ill. July 24, 2012) (taking judicial notice and considering "the text of the warning that has always been included in Pradaxa's labeling and prescribing information," even though "the exact language of the subject warning is not included in the plaintiff's complaint"). The relevant prescribing information is attached as Exhibit 1 to Lilly's Motion, and is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021427s049lbl.pdf.

2 DOSAGE AND ADMINISTRATION

…

2.7 Discontinuing CYMBALTA

Adverse reactions after discontinuation of CYMBALTA, after abrupt or tapered discontinuation, include: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible *[see Warnings and Precautions (5.7)]*.

…

5 WARNINGS AND PRECAUTIONS

…

5.7 Discontinuation of Treatment with CYMBALTA

Discontinuation symptoms have been systematically evaluated in patients taking CYMBALTA. Following abrupt or tapered discontinuation in adult placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in CYMBALTA-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue.

During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g. paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with CYMBALTA. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate *[see Dosage and Administration (2.7)]*.

[Filing No. 14-1 at 5-8 (brackets in original).] Additionally, the warnings quoted above are summarized on the first page of the prescribing information. [Filing No. 14-1 at 2.]

At all times relevant to this lawsuit, Mr. Ludy has been incarcerated in Georgia. [Filing No. 1 at 4.] In 2015, he went to the medical department at the prison with back pain, and an x-ray was ordered. [Filing No. 1 at 4.] Following the x-ray, Dr. Seward, the prison doctor, diagnosed Mr. Ludy with "cervical spine multilevel degenerative disk disease." [Filing No. 1 at 4.] After additional tests and doctor's visits, Mr. Ludy was diagnosed with "cervical spondylosis (a/k/a degenerative disk disease)." [Filing No. 1 at 4.] Initially, Mr. Ludy was prescribed 600mg of Neurontin twice a day to treat his nerve pain in his back. [Filing No. 1 at 4.] He took Neurontin from 2015 until 2017, when he was prescribed 30mg of Cymbalta. [Filing No. 1 at 4.]

At the time he was prescribed Cymbalta, Mr. Ludy questioned his doctor about the known side effects of the drug, and, while the doctor explained the side effects, the doctor "knew of no known *withdrawal* side effects." [Filing No. 1 at 4 (emphasis added).] Mr. Ludy alleges that within three weeks of starting Cymbalta, he experienced the following side effects: "urination hesitation, nausea, dizziness, suicid[al] thoughts, increased sweating, headaches, and anxiety." [Filing No. 1 at 4.] Mr. Ludy suffered those side effects throughout his use of Cymbalta. [Filing No. 1 at 4.]

Mr. Ludy first experienced withdrawal symptoms when the nurse working the "pill-call window" overlooked that he needed a refill of his medication. [Filing No. 1 at 5.] Mr. Ludy also suffered withdrawal symptoms when he would periodically attempt to stop taking Cymbalta because of the side effects. [Filing No. 1 at 5.] His withdrawal symptoms included "extreme mood swings, agitation, irritability, nightmares, suicidal thoughts, dizziness, electric shock sensation in [his] head, memory loss, vertigo, depression, and sleep disturbances." [Filing No. 1 at 5.] Mr. Ludy alleges that his withdrawal symptoms were dangerous and so severe that he would

immediately resume taking Cymbalta again to relieve the withdrawal symptoms. [Filing No. 1 at 5.]

Mr. Ludy alleges that if he

> had known the withdrawal symptoms or side effects he would [have] refused the Cymbalta, and if his physician would [have] known more about the drug then the Plaintiff['s] physician would have been able to more adequately, accurately and properly weigh and convey the risks and benefits of the drug in a way as to avoid the Plaintiff['s] injuries and damages.

[Filing No. 1 at 6.] Mr. Ludy adds that his physician would not have prescribed Cymbalta if his physician had been "adequately, accurately, and properly warned about the withdrawal symptoms," including their frequency, severity, and duration. [Filing No. 1 at 5.]

Mr. Ludy brought this lawsuit to recover for "personal injuries and damages that [he] suffered as a result of [Lilly's] failure to provide adequate instructions for stopping Cymbalta that would of (sic) adequately warned the Plaintiff fully and accurately about the frequency, severity, and/or duration of the Cymbalta symptoms." [Filing No. 1 at 6.] Specifically, he states his intention to bring claims against Lilly and other unidentified defendants for "negligence, design defect, failure to warn, stric[t] product liability, negligent misrepresentation, fraud, and breach of implied warranty, as well as violation of Georgia fair business practice act [("FBPA")]." [Filing No. 1 at 7.] Mr. Ludy requests that: "1) All future withdrawal side effects be paid by [Lilly], including but not limited to hospitalization; 2) [the Court] order Defendants to pay $90,000.00 compensatory and 1.6 million in punitive damages; 3) Defendants pay court cost and attorney fees; [and] 4) [the] Court grant other just and equitable relief." [Filing No. 1 at 8.]

On March 13, 2020, Lilly filed its Motion to Dismiss Mr. Ludy's claims, [Filing No. 14], which is now ripe for the Court's decision.

III.
DISCUSSION

In support of its Motion to Dismiss, Lilly argues that the warnings in Cymbalta's prescribing information regarding potential discontinuation symptoms are adequate as a matter of law, which defeats Mr. Ludy's failure to warn and negligence claims. [Filing No. 15 at 7.] It argues that "the FDA-approved label for [Cymbalta] has included an explicit, three-paragraph warning on the risk of symptoms" upon discontinuation of the drug. [Filing No. 15 at 7.] Lilly asserts that contained within those paragraphs are a clear statement of the frequency of discontinuation symptoms, a recitation of specific symptoms possible upon discontinuation, and guidance for safe discontinuation of Cymbalta. [Filing No. 15 at 7-8.] Though Lilly acknowledges that the adequacy of drug warnings is generally a question of fact, it argues that the adequacy of the warning in this case is a question of law because the warning is "accurate, clear, and unambiguous." [Filing No. 15 at 9-10 (quoting *Weilbrenner v. Teva Pharm. USA, Inc.*, 696 F. Supp. 2d 1329, 1339 (M.D. Ga. 2010)).] Additionally, Lilly argues that because Georgia employs the learned intermediary doctrine, it fulfilled its duty to warn "by providing a complete and accurate warning in Cymbalta's prescribing information." [Filing No. 15 at 15.] Lilly also argues that Mr. Ludy's fraud and FBPA claims are duplicative of his failure to warn claim. Lilly adds that Mr. Ludy failed to plead his fraud claim with particularity as required by Rule 9(b), and that the FBPA claim does not apply to claims based upon conduct regulated by a federal agency—the FDA in this case. [Filing No. 15 at 15-16.]

Mr. Ludy responds that "[his] Complaint not only meets but exceeds the standards [that] govern the form of a complaint contemplated by Federal Rule of Civil Procedure 8(a), this Court

has subject matter jurisdiction in this matter, and the complaint sufficiently alleges consumer harm and damage." [Filing No. 24 at 2.] He argues that his Complaint is not unintelligible or confusing and satisfies Rule 8(a)'s requirement of a short and plain statement of the claim. [Filing No. 24 at 5.] Mr. Ludy contends that the Complaint "describes in more than necessary detail" that Lilly marketed Cymbalta without properly warning of the "withdrawal symptoms associated with stopping Cymbalta, including accurate[ly] reporting their frequency, severity . . . and/or duration." [Filing No. 24 at 6-7.] Mr. Ludy also argues that the Court has subject matter jurisdiction and therefore should not dismiss this case under Rule 12(b)(1)[2] and should force Lilly "to proceed under Rule 12(b)(6) or Rule 56, both of which places great restrictions on the district court's discretion." [Filing No. 24 at 8 (quoting *Williamson v. Tucker*, 645 F.2d 404, 415-16 (5th Cir. 1981)) (alterations omitted).]

Lilly replies by reiterating that the extensive warnings in the prescribing documents satisfy its "duty under Georgia law to warn prescribing medical professionals." [Filing No. 25 at 1.] It argues that Mr. Ludy fails to reconcile his allegation that Lilly failed to warn of the discontinuation side effects with Cymbalta's prescribing information. [Filing No. 25 at 1.] Lilly also contends that Mr. Ludy sets forth arguments that fail to address the relevant issues. [Filing No. 25 at 2-3.]

A. Failure to Warn and Negligence Claims

In product liability cases premised on a failure to warn, "Georgia law insists that a plaintiff show that the defendant had a duty to warn, that the defendant breached that duty, and that the breach proximately caused the plaintiff's injury." *Dietz v. Smithkline Beecham Corp.*, 598 F.3d

[2] Lilly's Motion to Dismiss is made pursuant to Rule 12(b)(6), not Rule 12(b)(1). [Filing No. 14 at 1 ("Defendant Eli Lilly and Company . . . moves pursuant to Fed R. Civ. P. 12(b)(6) to dismiss Plaintiff Mitchell Ludy's Complaint in its entirety.").]

812, 815 (11th Cir. 2010) (*citing Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999)).[3] In cases concerning prescription drugs, however, "Georgia employs the learned intermediary doctrine, which alters the general rule that imposes liability on a manufacturer for failing to warn an end user of the known risks or hazards of its products." *Id.* Under the learned intermediary doctrine:

> [A] prescription drug or medical device [manufacturer] does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication or medical devices involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities.

McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1279–1280 (11th Cir. 2002) and *Williams v. Am. Med. Sys.*, 548 S.E.2d 371 (Ga. Ct. App. 2001)) (internal quotations and alterations omitted).

"For a warning to be adequate, it must disclose 'the existence and extent of the risk involved.'" *Swicegood v. Pliva, Inc.*, 2010 WL 1138455, at *3 (N.D. Ga. Mar. 22, 2010) (quoting *Thornton v. E.I. Du Pont De Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994)). Whether a warning is adequate "depends upon the language used and the impression that such language is calculated to make upon the mind of the average user of the product," and must be evaluated in conjunction with the knowledge and expertise of those who may be reasonably expected to use or otherwise come in contact with the product. *Thornton*, 22 F.3d at 289. "The adequacy of drug warnings is generally a question of fact, but it can become a question of law where the warning is

[3] Although the parties did not discuss in detail which law applies in this case, they appear to agree that Georgia law applies in this case.

accurate, clear, and unambiguous." *Weilbrenner v. Teva Pharm. USA, Inc.*, 696 F. Supp. 2d 1329, 1339 (M.D. Ga. 2010) (internal quotations omitted).

The Cymbalta prescribing documents describe potential withdrawal or discontinuation side effects in three different places within the first seven pages alone. [*See* Filing No. 14-1 at 2; Filing No. 14-1 at 5; Filing No. 14-1 at 8.] The warnings are clear and unambiguous, especially when considered together with a prescribing physician's expertise, and in fact articulate and warn of the specific withdrawal symptoms from which Mr. Ludy suffered. [*Compare* Filing No. 1 at 1 (alleging that he suffered "withdrawal symptoms such as . . . extreme mood swings, agitation, irritability, nightmares, suicidal thoughts, dizziness, electric shock sensation . . . memory loss, vertigo, depression, and sleep disturbances") *with* Filing No. 14-1 at 8 (stating that patients discontinuing Cymbalta suffered from "dizziness, headache, nausea, diarrhea, paresthesia [(tingling sensations)], irritability, vomiting, insomnia, anxiety, hyperhidrosis [(excessive sweating)], and fatigue" and that patients discontinuing similar drugs suffered from many of the same symptoms as well as "agitation [and] sensory disturbances (e.g. paresthesias such as electric shock sensation)".][4]

Mr. Ludy has not alleged that Lilly failed to provide the prescribing information to his physician, or that Lilly made inadequate efforts to warn his physician.[5] *See McCombs*, 587 S.E.2d 594 (holding that the warning included in the package insert with a medical device fulfilled the manufacturer's duty to warn); *see also Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1370 (S.D. Fla.

[4] Indeed, other courts have found that the Cymbalta prescribing information is accurate, clear, and unambiguous. *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 404 (S.D.N.Y. 2014) ("The elements of the Cymbalta discontinuation warning portray with sufficient intensity the risk involved in taking the drug." (internal quotations omitted)).

[5] Indeed, Mr. Ludy's alleges that his physician informed him of the general side effects of the drug, indicating that his physician had been warned of at least some of dangers of the drug.

2007) (noting that, under Florida law, if the manufacturer provides the warnings to the physician, it does not matter whether the physician passes the warnings on to his or her patients, or whether the physician even reads the warnings); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 765 (Ky. 2004) ("[P]roviding an adequate warning to the prescribing physician relieves the manufacturer of its duty to warn the patient regardless of how or if the physician warns the patient."). Likewise, he has not alleged that Lilly provided his physician with other documents which indicated there were likely to be no withdrawal symptoms or that Lilly otherwise withheld the warnings regarding discontinuation side effects.

The adequacy of warnings is generally an issue of fact not for the Court to decide on a motion to dismiss, but this case presents an unusual situation. The prescribing information describes in detail the potential withdrawal side effects, including the withdrawal side effects from which Mr. Ludy alleges he suffered. Though the Court is required to accept Mr. Ludy's allegations as true, his allegations expressly track the warnings in the Cymbalta prescribing information, and his response entirely fails to reconcile his allegations with the accurate, clear, and unambiguous warnings contained in the prescribing information. In sum, the prescribing information contains the necessary warnings, and the warnings contained within the prescribing information are adequate as a matter of law.

Because the Court finds that Lilly did not breach its duty to warn, Mr. Ludy's negligence claim also fails. *See Goldstein, Garber & Salama, LLC v. J.B.*, 797 S.E.2d 87, 89 (Ga. 2017) ("It is well established that to recover for injuries caused by another's negligence, a plaintiff must show four elements: a duty, *a breach of that duty*, causation and damages." (emphasis added)).

Mr. Ludy's Complaint fails to sufficiently allege that Lilly breached its duty to warn and Lilly's Motion to Dismiss Mr. Ludy's failure to warn and negligence claims is **GRANTED**.

B. Fraud and Negligent Misrepresentation Claims

Generally, Federal Rule of Civil Procedure 8(a) requires a plaintiff to set forth "a short plain statement of the claim showing that the pleader is entitled to relief." However, a plaintiff alleging fraud or mistake "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Generally, this requires the plaintiff to "describe[e] the 'who, what, when, where, and how' of the fraud." *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 615 (7th Cir. 2011) (quoting *Pirelli Armstrong Tire Corp. Retiree Medical Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 441-42 (7th Cir. 2011)).

Mr. Ludy's Complaint does not state with particularity the circumstances or facts that give rise to his fraud and negligent misrepresentation claims. He has not identified a specific statement or other representation he believes to be false or fraudulent, nor does he identify when, where, by whom, or to whom those representations were made. Therefore, the Court **GRANTS** Lilly's Motion to Dismiss Mr. Ludy's fraud and negligent misrepresentation claims.

C. Design Defect Claim

Under Georgia law, to recover on a design defect claim, plaintiff must establish that: (1) the product's design is defective and (2) the defective design caused plaintiff's injuries. *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 711 F. Supp. 2d 1348, 1364 (M.D. Ga. 2010). , Mr. Ludy does not allege that Cymbalta's design was defective, nor do his allegations identify a defect. Therefore, the Court **GRANTS** Lilly's Motion to Dismiss his claim under a design defect theory. *See Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1344-45 (N.D. Ga. 2012) ("[B]ecause the complaint is silent as to a design or manufacturing defect, the Court cannot draw the reasonable inference that a design or manufacturing defect caused the . . . injuries.").

D. Breach of Implied Warranty of Fitness for a Particular Purpose Claim

Georgia law provides that "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under Code Section 11-2-316 an implied warranty that the goods shall be fit for such purpose." O.C.G.A. Code § 11-2-315. But, because a patient is legally deemed to rely on the physician and not the package labeling for this warning, Mr. Ludy cannot show that he was "relying on the seller's skill or judgment to select or furnish suitable goods," as is required to prove a claim for breach of implied warranty of fitness for a particular purpose. *Presto v. Sandoz Pharm. Corp.*, 487 S.E.2d 70, 75 (Ga. Ct. App. 1997) (quoting O.C.G.A. § 11-2-315). Therefore, the Court **GRANTS** Lilly's Motion to Dismiss this claim.

E. FBPA Claim

The FBPA proscribes "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce." O.C.G.A. § 10-1-393. "By its express language, the FBPA excludes claims based upon conduct that is regulated by a federal agency." *Kuchenmeister v. HealthPort Tech., LLC*, 309 F. Supp. 3d 1342, 1349 (N.D. Ga. 2018) (citing O.C.G.A. § 10–1–396 ("Nothing in this part shall apply to: (1) Actions or transactions specifically authorized under laws administered by or rules and regulations promulgated by any regulatory agency of this state or the United States.")). As Lilly points out, Mr. Ludy's claim is based upon conduct that is regulated by the FDA, which bars this claim. [Filing No. 15 at 16.] Therefore, the Court **GRANTS** Lilly's Motion to Dismiss Mr. Ludy's FBPA claim.

IV.
CONCLUSION

Consistent with the foregoing, Lilly's Motion to Dismiss, [14], is **GRANTED**, and Mr. Ludy's Complaint is **DISMISSED WITH PREJUDICE**.[6] Final Judgment shall issue accordingly.

Date: 6/29/2020

Hon. Jane Magnus-Stinson, Chief Judge
United States District Court
Southern District of Indiana

Distribution via ECF only to all counsel of record.

Distribution via U.S. Mail to:

Mitchell Ludy
#1234896
Central State Prison
4600 Fulton Mill Road
Macon, GA 31208

[6] Additionally, Lilly's Motion to Stay Discovery, [30], is **DENIED AS MOOT**.